

REMARKS

Claims 23-30 are pending in the present application to which the Examiner asserts several rejections to which the Applicants respond in the following order:

- I. Claims 23-30 are rejected under 35 U.S.C. § 112 ¶ 1 for allegedly lacking enablement.
- II. Claims 23-26 are rejected under 35 U.S.C. § 112 ¶ 1 for allegedly failing to comply with the written description requirement
 - A. Ftn2 homolog vectors.
 - B. Ftn2 homolog essential nucleotide sequences
- III. Claim 29 is rejected under 35 U.S.C. § 112 ¶ 2 for allegedly being indefinite.

I. Claims 23-30 Are Enabled

The Examiner asserts that the specification allegedly does not provide enablement for Claims 23-30 because:

The claims are broadly drawn to a vector comprising any nucleic acids encoding proteins [comprising portions] of amino acids ... of SEQ ID NO:2 ...

Office Action pg. 3 ¶ 4. The Applicants disagree. The Applicants believe that the Examiner has mistakenly included Claims 27-30 in this rejection because Claim 27 recites the full SEQ ID NO:2, as amended in the last response, not amino acid sequence portions. As pointed out by the Applicants in the last response, the Examiner has admitted that the Applicants' specification enables SEQ ID NO:2.¹

In the present Office Action, the Examiner has also admitted that the:

The instant specification, however, only provides guidance for ... identification of potential Ftn2 homologues from various database sequences (example 3);

Final Office Action pg 3 – pg 4. Indeed, these Ftn2 homologs were the basis for the SEQ ID NO: 2 amino acid portions introduced in the previous response. The Applicants argue that these

¹ Because of this oversight the Applicants believe that Claims 27-30 should have been allowed in the present Office Action. Moreover, this shows that making the Office Action “final” was not proper.

portions are ‘common core sequences’ found by comparing the overlap between these identified Ftn2 homologs as listed in Applicants’ Specification Example 3 Table 3. For the Examiner’s convenience, the Applicants provide the following chart showing the amino acid identity relationships between SEQ ID NO: 2 and the identified Ftn2 homologs, resulting in eight (8) ‘common core sequences’ as recited in Claim 1:

<i>Group I (747-801)</i>	<i>Group IV (316-381)</i>	<i>Group VII (186-221)</i>
642-801	305-488	121-258
671-801	316 -409	173- 221
693-801	286- 381	129-287
683-801	286-384	186 -362
679-801	267-413	165-294
747-801	249-457	
710-801	290-472	
679-801		
708-801		
<i>Group II (679-799)</i>	<i>Group V (244-277)</i>	<i>Group VIII (95-121)</i>
673-798	165-294	1-177
669- 799	244-277	33-239
679-798	200-366	95-121
	211-358	
<i>Group III (623-691)</i>		
613-752		
585- 691		
623-717		

Groups I – VIII were constructed by identifying sets of Ftn2 homologues, as listed in Table 3, that have overlapping regions of SEQ ID NO: 2 homology. Then, a core sequence was identified for each Group that was common to each homologue within each set (see bolded amino acid residue numbers). Clearly, contrary to the Examiner’s conclusion, the Applicants’ specification does teach one having ordinary skill in the art how to make the full scope of the claimed nucleic acids.

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 1 to recite “... an Arabidopsis Ftn2 nucleic acid sequence encoding ...” and the sequence portions related to the ESTs in Table 3 were deleted. *Applicants’ Specification Example 3 and Figures 4-6 & 8*. Other grammatical amendments were also made

to Claim 1 in order to improve clarity. These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application. The Applicants have also added three sets of new claims: i) Claims 31-34 describing a vector comprising SEQ ID NO: 2; ii) Claims 35-38 describing a vector comprising a nucleic acid encoding cyanobacterial Ftn2 homolog proteins; and ii) Claims 39-42 describing a vector comprising a nucleic acid encoding *Oryza* (i.e., rice) Ftn2 homolog proteins:

Tblastn search with AtFtn2 and *Synechococcus* sp. WH8102 Ftn2 proteins as a query revealed homologues in all publicly available fully sequenced cyanobacterial genomes and also in rice (*Oryza sativa*) non-annotated genomic DNA sequence (Table 3).

Applicants' Specification, pg 92 ln 11-13.

The Applicants submit that Claim 1 is not consistent with the Examiner's statement that:

The claimed nucleic acids encode proteins with only 27 to 122 amino acids of SEQ ID NO:2; the remainder of the protein, if there is any at all, can be of any sequence.

Final Office Action, pg. 4.

The Examiner has also stated that:

The specification also does not teach how to use plants in which Ftn2 is overexpressed. The phenotype of such plants is not taught ...

Final Office Action pg. 7. The Applicants disagree because the Applicants' Specification does provide these teachings, for example:

In other embodiments, the present invention provides plants, seeds, plant cells and or plant parts comprising any of the above-described constructs. Plants are transformed with a heterologous gene encoding an Ftn2, ARCS, or Fzo-like protein or transformed with a fusion gene encoding a fusion polypeptide expressing an Ftn2, ARCS, or Fzo-like protein according to procedures well known in the art. It is contemplated that the heterologous genes are utilized to alter the level of the proteins encoded by the heterologous genes. It is further contemplated that the heterologous genes are utilized to change the phenotype of the transgenic plants; such changes in phenotype are contemplated to include but not be limited to change in plastid size, number per cell, and shape.

Applicants' Specification pg 70, ln 7-16 [emphasis added].

The Applicants respectfully request the Examiner withdraw the enablement rejection.

II. The Specification Provides A Sufficient Written Description For Claims 23-26

A. Vectors Are Adequately Described

The Examiner states that:

Neither the instant specification nor the originally filed claims appear to provide support for vectors comprising any nucleic acids encoding proteins of amino acids ... of SEQ ID NO: 2.

Final Office Action, pg. 2. The Applicants disagree and submit that the Applicants' Specification provides broad-based support for vectors comprising nucleic acid sequences, some of which are taught to encode SEQ ID NO: 2 (i.e., for example, SEQ ID NOS:1 & 3), for example:

In particular, some embodiments of the present invention provide recombinant constructs comprising one or more of the nucleic sequences as broadly described above (e.g., SEQ ID NOS: 1, 3, 4, 11, 14, 19, and 22). In some embodiments of the present invention, the constructs comprise a vector, such as a plasmid or viral vector, into which a nucleic acid sequence of the invention has been inserted, in a forward or reverse orientation. In preferred embodiments of the present invention, the appropriate nucleic acid sequence is inserted into the vector using any of a variety of procedures. In general, the nucleic acid sequence is inserted into an appropriate restriction endonuclease site(s) by procedures known in the art.

Large numbers of suitable vectors are known to those of skill in the art, and are commercially available. Such vectors include, but are not limited to, the following vectors: 1) Bacterial -- pQE70, pQE60, pQE-9 (Qiagen), pBS, pD10, phagescript, psiX174, 25 pbluescript SK, pBSKS, pNH8A, pNH16a, pNH18A, pNH46A (Stratagene); ptrc99a, pKK223-3, pKK233-3, pDR540, pRIT5 (Pharmacia); and 2) Eukaryotic -- pWLNEO, pSV2CAT, pOG44, PXT1, pSG (Stratagene) pSVK3, pBPV, pMSG, and pSVL (Pharmacia). Any other plasmid or vector may be used as long as they are replicable and viable in the host. In some preferred embodiments of the present invention, plant expression vectors comprise an origin of replication, a suitable promoter and enhancer, and also any necessary ribosome binding sites, polyadenylation sites, splice donor and acceptor sites, transcriptional termination sequences, and 5' flanking nontranscribed sequences. In other embodiments, DNA sequences derived from the SV40 splice, and polyadenylation sites may be used to provide the required nontranscribed genetic elements.

Applicants' Specification, pg 67 ln 14 – pg 68 ln 4 [emphasis added]. The Examiner should note that these two exemplary paragraphs are part of a larger section entitled “Vectors for Production of Plastid Division and Related Proteins”. Vectors are also discussed, in detail, within the Applicants' Specification from pg 71 ln 6 to pg 78 ln 9. Further, the use of a vector system with Ftn2 nucleotides is explicitly demonstrated in Example 1 (*Applicants' Specification pg. 85 ln 10-24*). Consequently, the Applicants' Specification provides adequate support to create any vector comprising an Ftn2-related nucleotide sequence.

Even so, the Examiner concludes by stating that:

The specification provides no support for any protein comprising amino acids 679-799, amino acids 316-318, and amino acids 186-221 of SEQ ID NO: 2.

Final Office Action, pg. 2. The Applicants disagree and believe that the above claim amendments clarify that the claimed embodiment is disclosed in Table 3 and demonstrates that one having ordinary skill in the art would be able to identify and define these groups. Further, the Examiner is suggesting that the specification recite, verbatim, exactly what is recited in the claims. There is well settled case law holding that the contextual presentation of claim limitations within an application is not relevant. In order to satisfy the written description requirement, the disclosure as originally filed need not provide *ipsis verbis* support for the claim subject matter at issue:

... *ipsis verbis* disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. *In re Edwards*, 568 F.2d 1349 ... (CCPA 1978).

Fujikawa v. Wattansasin, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir. 1996) [emphasis added]. The Applicants' claimed embodiments are disclosed in the specification in a manner that reasonably conveys to persons skilled in the art that the inventor had possession of the claimed subject matter and does not constitute new matter. Consequently, the Applicants' Specification does provide adequate written description for the presently claimed embodiment.

The Applicants respectfully request that the Examiner withdraw the Written Description rejection.

B. The Ftn2 Homologs Are Adequately Described

The Examiner states that:

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs:1, 3 and 4 are insufficient to describe the claimed genus.

Hence, Applicant has not, in fact, described a nucleic acid that encodes [portions] ... of SEQ ID NO: 2, wherein the nucleic acid encodes a product that functions in photosynthetic prokaryote or plastid division, within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Final Office Action pp 9-10. The Applicants disagree. As noted above, the Applicants' Specification provides a listing of Ftn2 homologs and their amino acid homology to SEQ ID NO: 2, but also their respective Accession numbers. These Accession numbers provide easy access for one having ordinary skill in the art to view the sequences and obtain the relevant literature associated with each Ftn2 homolog. That is all the law requires:

...[t]he applicant must ... convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir., 1991). Further, the Examiner is apparently arguing that the specification must provide specific listing of 'essential gene structure' for all the proposed Ftn2 homologs. This is contrary to current patent law interpreting the written description requirement:

Specifically, we hold ... that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met ... even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006) [emphasis added]. In *Falkner*, the very issue of ‘essential regions’ of nucleic acids was analyzed. The Federal Circuit clearly distinguished *Eli Lilly* as not setting a *per se* rule:

However, it is the binding precedent of this court that *Eli Lilly* does not set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art. See, *Capon*, 418 F.3d at 1357 (“None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., *Regents v. Lilly*, *Fiers v. Revel*, *Amgen*, or *Enzo Biochem*, require a redescription of what was already known.”). Thus, “[w]hen the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh.” *Id.* at 1358. ... Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement.

Falkner at 1367-68. Clearly, the Applicants’ description of the required structure(s) in regards to SEQ ID NO: 2 (i.e., the Ftn2 protein), in combination with the Accession numbers for the identified Ftn2 homologs, is in compliance with the written description requirement. The Applicants submit that the full length homologs disclosed in Table 3 (in addition to the found EST homologs) provide reference (via Accession numbers) to complete and known sequences.

The Applicants respectfully request that the Examiner withdraw the written description requirement.

III. Claim 29 Is Not Indefinite

The Examiner states that:

It is not clear in claim 29 if the plant seed comprises the heterologous gene. Not all seeds of a transgenic plant will comprise the nucleic acid with which the plant has been transformed.

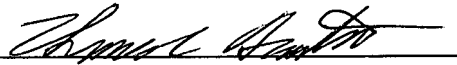
Office Action pg 10 ¶ 6. The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 29 to clarify that the seed comprises “said heterologous gene”. This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants respectfully request that the Examiner withdraw the Indefiniteness rejection.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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